

## REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claims 1-12 are pending in this application. Non-elected claims 6 and 8 are withdrawn from consideration by the Examiner.

Claim 1 is amended to become an independent claim by reciting the preamble from claim 5, the result of which claim 5 is cancelled.

Claims 3, 4, and 12 are amended to depend from claim 1.

Claims 2, 7 and 9-11 are cancelled.

### I. Acknowledgement of Foreign Priority

Applicants respectfully request the Examiner to expressly acknowledge Applicants claim for foreign priority under 35 U.S.C. § 119(a)-(d), and expressly acknowledge that the certified copy of the priority document has been received by checking the appropriate box on the Office Action Summary page of the next Official Action.

### II. Claim Rejection Under 35 U.S.C. § 112, First Paragraph

The Examiner rejects claims 1, 3, 4, 5 and 12 under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for showing the preparation of various dosage forms and for the preparation of compounds having a CCR antagonist effect, does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with the claims. By this Amendment, claim 5 is cancelled, rendering its rejection moot. As to the remaining claims, Applicants respectfully traverse the rejection.

One of ordinary skill in the art would be capable of practicing the claimed invention without undue experimentation. Claim 1 recites a method comprising administering an effective amount of a compound of formula (I) or a salt thereof, and claims 3 and 4 recite specific compounds and salts of formula (I). Furthermore, the specification teaches one of ordinary skill in the art how to make and use the compounds recited in claims 1, 3 and 4, and teaches how to practice the method recited in claim 1 (see page 304, line 8 – page 324, line 1).

In particular, the Experimental Example on pages 321-322 of the specification discloses the effects of a compound with respect to a mouse skin graft rejection model. The abdominal

skin of a donor mouse was grafted onto a recipient mouse, and 10 mg/kg of N,N-dimethyl-N-[4-[[[2-(4-methylphenyl)-6,7-dihydro-5H-benzocyclohepten-8-yl]carbonyl]amino]benzyl] tetrahydro-2H-pyran-4-ammonium chloride (a compound of formula (I) as recited in claim 1, and one of the species of claim 4), was administered subdermally thereto once a day from the day of grafting. A significant graft rejection suppression effect was observed with the administration of the compound.

Accordingly, one of ordinary skill in the art would have a reasonable expectation of the medicinal effects from the CCR antagonistic activity of compounds of formula (I), and salts thereof, in view of the present claims and the teachings of the specification. Therefore, one of ordinary skill in the art would be capable of practicing the claimed method without undue experimentation.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

### **III. Claim Rejection Under 35 U.S.C. § 102**

#### **A. Miki et al.**

The Examiner rejects claims 1-5, 7 and 9-12 under 35 U.S.C. § 102(e) as being anticipated by Miki et al. (US 2006/0094877). By this Amendment, claims 2, 5, 7 and 9-11 are cancelled, rendering their rejection moot. As for the remaining claims, Applicants respectfully traverse the rejection.

Claim 1 recites a method of treating graft-versus host disease and/or rejection reactions during heart, kidney, liver or bone marrow transplantation comprising a compound of formula (I) or a salt thereof. The Examiner asserts that the reference teaches Compound X in the treatment of graft-versus host disease. However, the reference does not teach a method of treating graft-versus host disease, but rather teaches a method of treating AIDS. See paragraph [0145] of the reference.

Because the reference does not teach a method of treating graft-versus host disease and/or rejection reactions during heart, kidney, liver or bone marrow transplantation, the reference does not teach each and every feature of claim 1. Therefore, claim 1 is not anticipated by the reference.

Claims 3, 4 and 12 depend from claim 1, and thus also are not anticipated by the reference.

**B. Imamura et al.**

The Examiner also rejects claims 1-4, 9 and 10 under 35 U.S.C. § 102(e) as being anticipated by Imamura et al. (US 6,562,978). By this Amendment, claims 2, 9 and 10 are cancelled, rendering their rejection moot.

With respect to claim 1, the Examiner states that the original rejection was solely directed to claims drawn to “agents,” and claim 5, a method of use claim, was not included in this rejection. By this Amendment, claim 1 is amended to recite the preamble of claim 5. Therefore, the rejection of claim 1 is moot in view of the amendments to recite the preamble of claim 5.

Claims 3 and 4 depend from claim 1, and thus the amendments to claim 1 also render the rejection of claims 3 and 4 moot.

**IV. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are earnestly solicited.

Should the Examiner find that anything further would be desirable in order to place the application in better condition for allowance, she is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

Noboru TSUCHIMORI et al.

By: 

Andrew B. Freistein  
Registration No. 52,917  
Attorney for Applicants

WMC/ABF/rgf  
Washington, D.C. 20005-1503  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
June 30, 2009